

REMARKS

The Applicants thank the Examiner for reviewing the present application. In particular, the Applicants would like to thank the Examiner for indicating in the January 14, 2004 Office Action that Claims 31-36 and Claims 38-40 are in a condition for allowance.

Amendments to the Claims

The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the instant application with the listing of claims provide. Claims 1, 31, 38, 39 and 40 were amended.

35 U.S.C. §112, ¶1 Enablement Rejections

The Examiner has rejected Claims 1-13 as allegedly lacking enabling support in the specification commensurate in scope to the claimed invention. Specifically, the Examiner contends that the specification fails to provide enough information that would allow a person skilled in the art to practice the claimed invention without undue experimentation. The Applicants respectfully traverse this rejection and ask for reconsideration under 37 C.F.R. §1.111.

As cited in the *Manual of Patent Examining Procedure*, 8th edition, February 2003 revision (hereafter the "MPEP"), the courts have routinely interpreted the standard for determining enablement under 35 U.S.C. §112, ¶1 as follows:

The test of enablement is whether one reasonably skilled in the art could **make** or **use** the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)

Furthermore, case law and the MPEP clearly indicate that **only one embodiment** characteristic in scope of the claimed invention is necessary to satisfy the enablement requirement of 35 U.S.C. 112, ¶1. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970), MPEP §2164.01(b) and (c).

First, the Examiner contends that not enough information is disclosed in the instant specification to allow one skilled in the arts to practice the claimed invention without undue experimentation. However, the Applicants have clearly disclosed how to make and use a method for the treatment of an FXR-mediated pathological condition. As indicated in the January 14, 2004 Office Action, the Examiner acknowledges that the instant specification enables one skilled in the art to practice the claimed invention in the treatment of specific FXR-mediated pathological conditions, namely dyslipidemia, hypercholesterolemia and hypocholesterolemia. The Applicants agree that the instant specification discloses how to make and use three specific embodiments of the claimed invention. The Applicants respectfully point out that the instant specification, therefore, directly discloses how to use a method for treating FXR-mediated pathological conditions. Furthermore, by explicitly acknowledging that use of the disclosed method is enabling for these specific FXR-mediated pathological conditions, the Examiner has implicitly acknowledged that the instant specification discloses how to make the required compound formulations and how to deliver

these compounds to a mammal afflicted with a FXR-mediated pathological conditions (i.e., to use the method). Therefore, with the Examiner's own acknowledgment, the instant specification provides sufficient disclosure to allow one skilled in the art to practice the claimed invention without undue experimentation.

Second, the Examiner argues that the claims of the invention are too broad. The Applicants respectfully submit that the instant specification clearly seeks claim protection that is commensurate in scope with the enablement provided. The claims are directed towards a method of treating FXR-mediated pathological conditions. Examples of specific FXR-mediated pathological conditions disclose how to make and use the claimed invention. Hence, one skilled in the art would find a reasonable correlation that the disclosed FXR modulating compounds will modulate FXR signaling in other FXR-mediated pathological conditions. Therefore, the instant specification provides sufficient disclosure to allow one skilled in the art to practice the entire scope of the claim invention.

Furthermore, the Applicants respectfully submit that the Examiner failed to meet the initial burden of establishing a reasonable basis to question enablement as required by *MPEP* §2164.04. The Examiner 's arguments for non-enablement appears based on personal opinion rather than technical reasons or specific findings of fact supported by the evidence. Specifically, the Examiner failed to prove: 1) why the disclosed compounds used to carry out the claimed method for the enabled embodiments would not enable one skilled in the art to practice the method on further embodiments; or 2) why the disclosed means to carry out the claimed method for the enabled embodiments would not enable one skilled in the art to practice the method on further embodiments.

Third, the Examiner contends that the specification fails to set forth criteria that define "FXR-mediated pathological conditions." The Applicants respectfully submit that the phrase "FXR-mediated pathological conditions" is the most precise and accurate term the Applicants can use to describe the conditions the claimed invention will treat. The method employs compounds from the formula 3 genus that modulate FXR signaling. Modulation of FXR signaling is a critical aspect of the claimed invention. The method, therefore, is directed toward treating FXR-mediated pathological conditions. Any other term, such as a limitation to a specific condition, would result in the scope of the invention becoming either too narrow or too broad.

Fourth, the Examiner raises concern that claimed invention is directed towards FXR-mediated pathological conditions not yet discovered. The Applicants respectfully point out that it is not necessary nor required that every FXR-mediated pathological condition be disclosed in the instant specification. It is perfectly valid to claim a method of treatment for a heretofor unknown condition. In fact, as pointed out in the *MPEP*, the Court of Customs and Patent Appeals (CCPA) has specifically indicated that:

[T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

In re Goffe, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976). See also *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)

Therefore, the Applicants respectfully submit that the instant specification clearly enables one skilled in the art to practice (i.e. make and use) the claimed invention without undue experimentation. The Applicants have taught one skilled in the art how to make a method of treating an FXR-mediated pathological condition in a mammal by providing numerous compounds from the formula 3 genus. The Applicant's have disclosed how one skilled in the art can use a method of treating an FXR-mediated pathological condition in a mammal by providing three instructional examples that employ the method. Lastly, since each method of treatment uses species compounds from the formula 3 genus and targets the same FXR signaling pathway, there is a reasonable correlation that the examples given correlate with the entire scope of the claimed invention. The Applicants respectfully submit that the Examiner's assertion that the specification did not disclose how to practice the claimed invention without undue experimentation is without merit.

For these reasons the Applicants respectfully request withdrawal of the 35 U.S.C. §112, ¶1 enablement rejections for Claims 1-13.

CONCLUSION

For the above reasons the claims are now thought to be in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. Please use Deposit Account 01-0885 for the payment of the extension fees or any other fees due in connection with the current response.

Respectfully submitted,



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